

REMARKS

Claims 31-64 are pending in the application. Claims 31, 37, 39, 48, 50, 51, and 52 have been amended herein without prejudice to state that the extracellular matrix is produced by the cultured fibroblast cells or cultured dermal fibroblast cells in the absence of both exogenous matrix components and a mesh member during the culturing conditions. Support for this language is found in the specification at, *inter alia*, page 10, lines 21-29, which states in part as amended that the "cultured tissue constructs of the invention do not rely on synthetic or bioresorbable members, such as a mesh member for the formation of the tissue constructs."

Applicants note that MPEP §2173.05(i) states that the "current view of the courts is that there is nothing inherently ambiguous or uncertain about a negative limitation. So long as the boundaries of the patent protection sought are set forth definitely, albeit negatively, the claim complies with the requirements of 35 U.S.C. 112, second paragraph." Applicants therefore respectfully assert that the above amendment is proper.

Claims 65-71 have been added herein. These claims are based on previous claims 31, 37, 39, 48, 50, 51, and 52, which have been rewritten as claims 65-71 herein to indicate that the extracellular matrix is synthesized and assembled by the cultured fibroblast cells on one surface of a porous membrane or that the extracellular matrix is produced by the cultured fibroblast cells on one surface of a porous membrane in the absence of exogenous matrix components during the culturing conditions. Support for these claims is the same as for previous claims 31, 37, 39, 48, 50, 51, and 52. In addition, support for the added language can be found in the specification at, *inter alia*, page 9, line 11 to page 10, line 20.

Accordingly, no new matter has been introduced by these amendments and new claims.

Therefore, after entry of this amendment, claims 31-71 will be pending in this application.

Applicants respectfully request that the Examiner initial and return copies of the PTO Forms 1449 submitted with the Information Disclosure Statements filed April 12, 2001 and September 17, 2002.

Applicants thank Examiner Sumesh Kaushal and his supervisor, Examiner Jeffrey Fredman, for their time in participating in a personal interview on January 27, 2005 with Edward J. Adamson and Alison Corkery.

Applicants' representatives showed the Examiners a sample of a product covered by the claimed embodiments of the invention. Examiner Fredman indicated that based on a review of the specification the enablement rejection would probably be withdrawn. Applicants' representatives and the Examiners discussed the outstanding rejections under 35 U.S.C. § 102 and 103 as well as possible types of amendments to clarify the differences from the cited references.

The outstanding rejections are addressed individually below.

I. Claims 31-64 are enabled by the specification as filed.

The outstanding Office Action states that claims 31-64 are rejected under 35 U.S.C. § 112, first paragraph, for allegedly failing to comply with the enablement requirement. Applicants respectfully traverse this rejection.

M.P.E.P § 2164.01 states that 35 U.S.C. § 112, first paragraph, "has been interpreted to require that the claimed invention be enabled so that any person skilled in the art can make and use the invention without undue experimentation." The same section further states that "[t]he fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation."

The specification does teach one of skill in the art how to *make* the claimed invention. *See, e.g.*, the specification at page 7, lines 4-19 (disclosing various sources of fibroblast cell strains), at page 9, line 1 to page 10, line 20 (teaching suitable vessels and growth surfaces), at page 11, line 11 to page 17, line 24 (teaching culture media formulations), at page 17, lines 25-28 (describing environmental conditions), at page 17,

line 29 through page 18, line 26 (teaching seeding and culturing the fibroblasts in order to obtain a layer of cultured fibroblasts and extracellular matrix), and at page 19, line 7 to page 20, line 11 (teaching application of an epithelial cell layer to the construct).

Additionally, the specification does teach one of skill in the art how to *use* the claimed invention. *See, e.g.*, the specification at page 24, line 7 to page 25, line 4 (teaching methods for grafting the skin construct of the invention to a patient).

Therefore, the specification has fully enabled the invention as claimed because it teaches how to make and use the claimed invention without undue experimentation.

Applicants respectfully submit that these claims are enabled by the specification as filed. As discussed in the interview on January 27, 2005, Applicants understand that after further consideration by the Examiner this rejection is being withdrawn.

Therefore, Applicants respectfully request that the Examiner reconsider and withdraw this rejection.

II. Claims 31-32, 36-38, and 48-49 are not anticipated under 35 U.S.C. § 102(b).

Claims 31-32, 36-38, and 48-49 stand rejected as allegedly being anticipated by Fleishmajer *et al.* under 35 U.S.C. § 102(b). Applicants respectfully traverse this rejection.

M.P.E.P. 2131 provides that:

“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). . . . “The identical invention must be shown in as complete detail as is contained in the . . . claim.” *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Applicants respectfully submit that they do not necessarily agree with the characterization of Fleishmajer *et al.* and that the claims prior to amendment are not anticipated by the Fleishmajer *et al.* for the reasons of record. However, in order to

expedite prosecution, Applicants have amended the independent claims further to clarify this fact.

Thus, Applicants submit that the claims as amended are not anticipated by Fleishmajer *et al.*, and the § 102(b) rejection is unsupported by the art. Applicants respectfully request reconsideration and withdrawal of this rejection.

III. Claims 33-35, 39-47, and 50-52 are not obvious under 35 U.S.C. § 103(a).

Claims 33-35, 39-47, and 50-52 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Fleishmajer *et al.* in view of Naughton *et al.* (U.S. Patent No. 5,266,480). Applicants respectfully traverse this rejection.

M.P.E.P. § 2142 states:

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure.

Applicants respectfully submit that they do not necessarily agree with the characterization of Fleishmajer *et al.* and Naughton *et al.* and that the claims prior to amendment are not obvious over the Fleishmajer *et al.* in view of Naughton *et al.* for the reasons of record. However, in order to expedite prosecution, Applicants have amended the independent claims further to clarify this fact.

Applicants respectfully submit that there is no *prima facie* case for obviousness based on these references. Accordingly, Applicants respectfully request that this rejection be reconsidered and withdrawn.

CONCLUSIONS

In view of the arguments set forth above, Applicants respectfully submit that the rejections contained in the Office Action mailed on October 1, 2004, have been overcome, and that the pending claims, claims 31-71, are in condition for allowance. If the Examiner believes that any further discussion of this communication would be helpful, he is invited to contact the undersigned at the telephone number provided below.

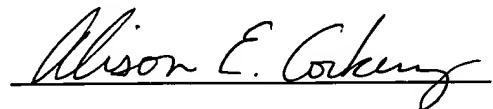
Applicants enclose herewith a petition for a two month extension of time pursuant to 37 C.F.R. § 1.136, up to and including March 1, 2005. Please charge Deposit Account No. 08-0219 the \$225.00 fee (small entity) for this purpose.

Applicants also enclose herewith a notice of appeal. Please charge Deposit Account No. 08-0219 the \$250.00 fee (small entity) for this submission.

Please also charge the \$875.00 fee (small entity) for seven additional independent claims to Deposit Account No. 08-0219.

No other fees are believed to be due in connection with this response. However, please charge any underpayments or credit any overpayments to Deposit Account No. 08-0219.

Respectfully submitted,



Alison E. Corkery
Reg. No. 52,770

Date: March 1, 2005
WILMER CUTLER PICKERING
HALE AND DORR LLP
60 State Street
Boston, MA 02109
Tel: (617) 526-6000
Fax: (617) 526-5000